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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,631	10/31/2001	Jonathan M. Graff	A34943-090495.0243	1939
7590	10/02/2003		EXAMINER	
			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	19

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/002,631	GRAFF ET AL.
	Examiner	Art Unit
	David A. Lambertson	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 114-144 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) 114-144 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Claims 1-113 have been cancelled by a preliminary amendment accompanying a petition to make special. Claims 114-144 are pending in the instant application, and a restriction requirement for said claims is presented below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 114-128 and 135-144, drawn to a method for identifying a candidate nucleic acid encoding a signal/transmembrane sequence, classified in class 435, subclass 6.
- II. Claim 129, drawn to a method of identifying the function of a polypeptide having a signal/transmembrane sequence, classified in class 435, subclass 7.4.
- III. Claims 130-134, drawn to a method of correlating the function of a nucleic acid or polypeptide having a signal/transmembrane sequence to a disease state or other physiological condition, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and functions, and are not disclosed as capable of being used together. Specifically, the outcome of Invention I is the identification of a nucleic

acid sequence that encodes an amino acid sequence with the capacity to traverse biological membranes, and this involves method steps where it is determined if such a sequence is encoded by the nucleic acid that is being tested. Invention II, however, requires different method steps and each polypeptide has a different function. In Invention II, it appears that the function of a polypeptide having a signal sequence is determined. Such a function could be quite variegated, as a number of proteins such as growth factors, hormones, transcription factors, receptor proteins, etc., each have signal/transmembrane sequences. These functions are clearly different from determining if a polypeptide has the ability to traverse a biological membrane, and therefore require different method steps to determine the activity associated with each polypeptide. Because these inventions have different functions and modes of operation (i.e., method steps), the inventions are patentably distinct.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and effects, and are not disclosed as capable of being used together. Specifically, the outcome of Invention I is the identification of a nucleic acid sequence that encodes an amino acid sequence with the capacity to traverse biological membranes, and this involves method steps where it is determined if such a sequence is encoded by the nucleic acid that is being tested. Invention III, however, requires different method steps and has a different function. In Invention III, it appears that the function of a polypeptide having a signal sequence is correlated to a disease condition. Determining whether a particular protein is associated with a disease state results in an outcome that is quite different from the basic

identification of a transmembrane sequence. This also requires different method steps, such as determining a disease state, showing that there is a corresponding mutation in a gene encoding a protein with a transmembrane sequence, etc. Because these inventions have different effects and modes of operation (i.e., method steps), the inventions are patentably distinct.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different outcomes, and require different modes of operation and are not disclosed as capable of being used together. Specifically, Invention II involves a determination of function for a polypeptide having a signal sequence. This requires biochemical examination to associate the polypeptide with a particular activity. Invention III, on the other hand, requires that one determine that a disease state is related to a mutation in a protein having a signal sequence. These are distinct method steps which result in different outcomes, the identification of a biochemical activity versus the correlation of a disease state with a mutated transmembrane sequence containing protein. Thus, the inventions have different effects and modes of operation, and are therefore patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-

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extensive, hence said searches would be burdensome. Therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
AU1636

Gerry Leffers
GERRY LEFFERS
PRIMARY EXAMINER